REMARKS

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61-62, 64-67, 69-70, 73, 75, 79, 81-85, 91-97, 101, 103 and 105 are pending in the application. By this Amendment, withdrawn Claim 32-33, 41, 43, 47, 60, 68, 71, 76, 86-90, 98-100, 106-107 are canceled, without prejudice or disclaimer. The Examiner indicated Claims 76 and 90 as withdrawn on page 2 of the Office Action. To reduce the issues, these claims are canceled, without prejudice or disclaimer.

Applicant thanks Examiners Graffeo and Marschel for the courtesies extended to his representative during the August 17, 2006 personal interview and to himself during his participation via telephone. Applicant's separate record of the interview is set forth in the foregoing amendments and the following remarks.

I. SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENTS

Applicant respectfully requests Examiner Graffeo to sign and return the Forms PTO-1449 submitted with: (1) the Supplemental IDS filed via certificate of mailing on March 26, 2001; (2) the Second Supplemental IDS filed via certificate of mailing on December 21, 2001; and (3) the Third Supplemental IDS filed via certificate of mailing on March 8, 2002. Copies of these Supplemental IDS's and the foreign references were presented to Examiner Graffeo during the August 17, 2006 personal interview. Consideration of the previously-submitted references is respectfully requested.

II. RESTRICTION REQUIREMENTS

The elected species are: (1) durum wheat as a plasticizable matrix material and (2) a probiotic neutraceutical component as an encapsulant. Applicant notes that the election

of species requirement directed to the rate-controlling agent (hydrophobic component/fat) was withdrawn in the Office Action dated March 17, 2003.

The Examiner chose plasticized starch as the next species of matrix material to be examined, after indicating that the durum wheat species is allowable. Applicant respectfully asserts that Claims 26 and 50 recite plasticized starch as a matrix material and thus should not be indicated as withdrawn, but as pending. For the next elected species, Applicant respectfully requests the Examiner to elect the species of plasticized matrix material already recited in independent Claims 52 and 83 and/or in dependent Claims 42, 69-70, and 84.

III. EXAMINER INTERVIEW

At the August 17, 2006 personal interview, Applicant's representative placed 0.5 mm pellets comprising plasticized hard wheat flour in water in a first clear plastic cup and placed 0.5 mm pellets comprising non-plasticized native wheat starch in water in a second plastic cup. All pellets were made by adding water to flour or starch inside an extruder, extruding the mixture through a die, cutting the extrudate into pieces, and then drying the pieces at room temperature.

After intermittent stirring of both plastic cups, the pellets comprising the native wheat starch quickly disintegrated and clouded the water. In contrast, the pellets comprising the plasticized hard wheat flour remained intact, although there was very slight cloudiness due to residual starch granules that are so small that they remained in suspension and settled over time. Thus, Applicant argued that native wheat starch, such as the dried starch of Mutai et al., is structurally different than plasticized starch and therefore has different properties.

Examiner Marschel asserted that starch production might inherently result in a plasticized starch since heat treatment is utilized in such processes.

IV. REJECTION UNDER 35 U.S.C. 103(a)

Claims 25, 27-31, 34, 35, 37-40, 42, 46, 52-59, 61-62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105 were rejected under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 4,187,321 (Mutai et al.). This rejection is respectfully traversed.

Mutai et al. discloses foods and drinks containing bifidobacteria prepared by growing, in a milk medium under aerobic conditions, a mixture of bifidobacteria containing a mutant strain of oxygen-resistant Bifidobacterium and a strain of anaerobic Bifidobacterium (Abstract). The Examiner cites Example 3 for disclosing starch and col. 2, lines 35-43 for disclosing fat. Example 3 discloses that freeze dried cells were mixed with a 20-fold volume of dried starch and tabletted. Col. 2, lines 35-43 discloses that the media for cultivating the bacteria may be whole milk.

Mutai et al. does not teach or suggest an encapsulated product comprising discrete, solid particles wherein each particle comprises an encapsulant dispersed throughout a plasticized mass or plasticized matrix material, as recited in independent Claims 25, 52, and 83.

As discussed in the paragraph bridging pages 8-9 of the specification, at least one plasticizable, matrix-forming material such as starch may be admixed with a sufficient amount of a plasticizer such as water to reduce the melt or glass transition temperature of the plasticizable material, together with the additional release-rate controlling ingredient. The mix is heated above the melt or glass transition temperature of the plastifiable or matrix material, such as above the gelatinization temperature of a starch matrix

ingredient, while conveying and mixing the ingredients within an extruder. The temperature is maintained sufficiently high for a sufficiently long period of time to at least partially gelatinize starch in the mixture. See also page 22 of the specification which was discussed at the interview.

There is no teaching or suggestion that the "dried starch" of Example 3 of Mutai et al. is a plasticized material. Thus, contrary to the Examiner's assertion, the product as claimed is not the same as that in the art (Office Action at page 3).

As noted, Examiner Marschel asserted that starch production might inherently result in a plasticized starch since heat treatment is utilized in such processes. However, any heat treatment up to about 50°C that occurs during starch processing does not result in plasticization, as shown by the references concurrently submitted with an Information Disclosure Statement.

Pomeranz, *Wheat is Unique*, discloses that the processing of wheat according to a modified Longford-Slotter process occurs with unmilled wheat being steeped in the laboratory for 15 hours at 37°C (page 521). See also pages 524-525 (Alsatin process) and 528 (Halle process). Similarly, in discussing the wet milling of wheat flour, Cornell et al. in *Wheat Chemistry and Utilization* states that at temperatures below 35°C, the starch does not gel and is able to be removed by centrifugation (pages 79-80). Likewise, in White et al., *Corn: Chemistry and Technology,* it states that the water used for corn starch washing

> is heated to 38-43°C to enable removal of soluble matter ... Temperature sensors in the hydroclone systems protect the starch slurry from temperature exceeding 54°C, well below the starch-pasting temperature of 63°C.

See page 465 (emphasis added).

In contrast, Whistler et al., *Starch: Chemistry and Technology*, show that the pasting or gelatinization temperature of starch is in the range of 52-63°C for wheat and 62-72°C for corn (Table 1, page 292). Likewise Table 6.1 on page 121 of Whistler et al., *Carbohydrate Chemistry for Food Scientists*, indicates gelatinization/pasting temperatures are in the range of 52-85°C for wheat and 62-80°C for corn.

Thus, starch production, particularly starch extraction, does not inherently result in plasticization of the starch because it occurs at temperatures lower than the pasting or gelatinization temperature. Further, plasticization/gelatinization causes disruption of the molecular order within starch granules, as evidenced by irreversible granule swelling, loss of birefringence, and loss of crystallinity (page 128 of Whistler et al., *Carbohydrate Chemistry for Food Scientists*).

In sum, evidence that the claimed plasticized mass or matrix material has a different structure and different properties than the dried starch of Mutai et al. was presented at the August 17, 2006 personal interview, is given by the concurrently-submitted references, and would be well known to one of ordinary skill in the art. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed encapsulated products in view of the teachings of Mutai et al. Reconsideration and withdrawal of the rejection are respectfully requested.

V. CONCLUSION

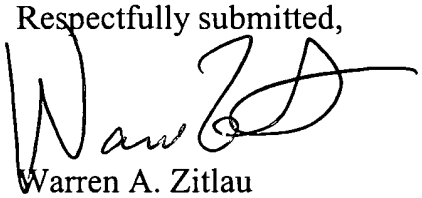
In light of the foregoing remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the

undersigned would be appreciated since this should expedite the prosecution of the application.

Any fees should be charged to, or any overpayment in fees should be credited to, Deposit Account No. 501032 (Docket #BVL-102A).

An Information Disclosure Statement is being filed concurrently herewith.

Respectfully submitted,



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CERTIFICATE OF MAILING

I hereby certify that this correspondence dated 9-15-06 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 9-15-06.

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